

Food and Drug Administration, HHS

§ 868.6820

drugs. The device is usually constructed to eliminate build-up of static electrical charges.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38796, July 25, 2001]

§ 868.6175 Cardiopulmonary emergency cart.

(a) *Identification*. A cardiopulmonary emergency cart is a device intended to store and transport resuscitation supplies for emergency treatment. The device does not include any equipment used in cardiopulmonary resuscitation.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38796, July 25, 2001]

§ 868.6225 Nose clip.

(a) *Identification*. A nose clip is a device intended to close a patient's external nares (nostrils) during diagnostic or therapeutic procedures.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38796, July 25, 2001]

§ 868.6250 Portable air compressor.

(a) *Identification*. A portable air compressor is a device intended to provide compressed air for medical purposes, e.g., to drive ventilators and other respiratory devices.

(b) *Classification*. Class II (performance standards).

§ 868.6400 Calibration gas.

(a) *Identification*. A calibration gas is a device consisting of a container of gas of known concentration intended to calibrate medical gas concentration measurement devices.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 868.6700 Anesthesia stool.

(a) *Identification*. An anesthesia stool is a device intended for use as a stool for the anesthesiologist in the operating room.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25049, June 12, 1989; 66 FR 38796, July 25, 2001]

§ 868.6810 Tracheobronchial suction catheter.

(a) *Identification*. A tracheobronchial suction catheter is a device used to aspirate liquids or semisolids from a patient's upper airway.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 868.9.

[47 FR 31142, July 16, 1982, as amended at 65 FR 2314, Jan. 14, 2000]

§ 868.6820 Patient position support.

(a) *Identification*. A patient position support is a device intended to maintain the position of an anesthetized patient during surgery.

§ 868.6885

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 868.6885 Medical gas yoke assembly.

(a) *Identification*. A medical gas yoke assembly is a device intended to connect medical gas cylinders to regulators or needle valves to supply gases for anesthesia or respiratory therapy. The device may include a particulate filter.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

PART 870—CARDIOVASCULAR DEVICES

Subpart A—General Provisions

Sec.

870.1 Scope.

870.3 Effective dates of requirement for premarket approval.

870.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Cardiovascular Diagnostic Devices

870.1025 Arrhythmia detector and alarm.
870.1100 Blood pressure alarm.
870.1110 Blood pressure computer.
870.1120 Blood pressure cuff.
870.1130 Noninvasive blood pressure measurement system.
870.1140 Venous blood pressure manometer.
870.1200 Diagnostic intravascular catheter.
870.1210 Continuous flush catheter.
870.1220 Electrode recording catheter or electrode recording probe.
870.1230 Fiberoptic oximeter catheter.
870.1240 Flow-directed catheter.
870.1250 Percutaneous catheter.
870.1270 Intracavitary phonocatheter system.
870.1280 Steerable catheter.
870.1290 Steerable catheter control system.
870.1300 Catheter cannula.
870.1310 Vessel dilator for percutaneous catheterization.

21 CFR Ch. I (4–1–02 Edition)

870.1330 Catheter guide wire.
870.1340 Catheter introducer.
870.1350 Catheter balloon repair kit.
870.1360 Trace microsphere.
870.1370 Catheter tip occluder.
870.1380 Catheter stylet.
870.1390 Trocar.
870.1425 Programmable diagnostic computer.
870.1435 Single-function, preprogrammed diagnostic computer.
870.1450 Densitometer.
870.1650 Angiographic injector and syringe.
870.1660 Indicator injector.
870.1670 Syringe actuator for an injector.
870.1750 External programmable pacemaker pulse generator.
870.1800 Withdrawal-infusion pump.
870.1875 Stethoscope.
870.1915 Thermodilution probe.

Subpart C—Cardiovascular Monitoring Devices

870.2050 Biopotential amplifier and signal conditioner.
870.2060 Transducer signal amplifier and signal conditioner.
870.2100 Cardiovascular blood flowmeter.
870.2120 Extravascular blood flow probe.
870.2300 Cardiac monitor (including cardiometer and rate alarm).
870.2310 Apex cardiograph (vibrocardiograph).
870.2320 Ballistocardiograph.
870.2330 Echocardiograph.
870.2340 Electrocardiograph.
870.2350 Electrocardiograph lead switching adaptor.
870.2360 Electrocardiograph electrode.
870.2370 Electrocardiograph surface electrode tester.
870.2390 Phonocardiograph.
870.2400 Vectorcardiograph.
870.2450 Medical cathode-ray tube display.
870.2600 Signal isolation system.
870.2620 Line isolation monitor.
870.2640 Portable leakage current alarm.
870.2675 Oscillometer.
870.2700 Oximeter.
870.2710 Ear oximeter.
870.2750 Impedance phlebograph.
870.2770 Impedance plethysmograph.
870.2780 Hydraulic, pneumatic, or photoelectric plethysmographs.
870.2800 Medical magnetic tape recorder.
870.2810 Paper chart recorder.
870.2840 Apex cardiographic transducer.
870.2850 Extravascular blood pressure transducer.
870.2860 Heart sound transducer.
870.2870 Catheter tip pressure transducer.
870.2880 Ultrasonic transducer.
870.2890 Vessel occlusion transducer.
870.2900 Patient transducer and electrode cable (including connector).